

## REMARKS

Claims 1, 6-37 and 43-46 are pending in the present application. Claims 38-42 are canceled herein. Claims 2-5 were canceled previously. The amendment to the specification lists the application to which the present application claims priority. This claim of priority was acknowledged on the filing receipt of the present application. Applicants thank Examiner George for withdrawing the objection to claim 23, the obviousness-type double patenting rejection of claims 1-10, 21, 22 and 24-34, and 35 U.S.C. § 103(a) rejection of claims 11-20 and 35 over Bollag *et al.*

Claims 1 and 6-47 are rejected under 35 U.S.C. § 103(a) as unpatentable over Tong *et al.* (U.S. 6,512,022 B2).

Applicants respectfully traverse the rejection. The Tong reference has a filing date of May 11, 2001. The present application is a divisional application of U. S. Ser. No. 09/631,151, filed August 2, 2000 and now issued as U. S. 6,339,107. The priority date of the present application, therefore, is August 2, 2000 and the Tong is not valid reference against the instant application. Withdrawal of the 35 U.S.C. § 103(a) rejection is respectfully requested.

The incorporation of essential material in the specification by reference to a foreign application of patent, or to a publication is improper. Applicant is required to amend the disclosure to include material incorporated by reference.

The Office Action alleges the specification must be amended to incorporate essential material from the following patents:

- (1) EP 959069 *A Process for the Preparation of 13-Cis-Retinoic Acid*
- (2) WO99/48866 *Process for the Preparation of 13-Cis-Retinoic Acid*
- (3) EP742204 *Photochemical Method for the Preparation of 13-Cis-Retinoic Acid*
- (4) WO97/39745 *Use of Inhaled Retinoids in the Prevention of Cancer*
- (5) WO94/12285 *Dispensing Device*
- (6) WO94/14543 *Dispensing Device*
- (7) WO95/26234 *Dispensing Device*
- (8) WO95/26235 *Dispensing Device*

Tong has  
priority dating  
back to a CIP of  
PCT/US97/05409  
4/21/97. Further  
back to a provisional  
dating 4/19/96

(9)WO9532807 *Dispensing Device*

Applicants respectfully disagree. The Office Action appears to identify every foreign application incorporated by reference and requests the specification be amended to explicitly disclose the referenced subject matter. No reason for the request was provided. The MPEP distinguishes between essential and nonessential subject matter and the latter may be incorporated by reference to foreign patents or patent applications.

"Essential Matter" is defined as that which is necessary to (1) describe the claim invention, (2) provide an enabling disclosure of the claimed invention, or (3) describe the best mode (35 U.S.C. 112) ...

Nonessential subject matter may be incorporated by reference to (1) patents or applications published by the United States or foreign countries or regional patent offices ... Nonessential subject matter is subject matter referred to for the purpose of indicating the background of the invention or illustrating the state of the art. (MPEP §608.01(p) I. A.)

All of the claims in the instant application are methods of treating lung diseases with 13-*cis*-retinoic acid or pharmaceutical compositions containing 13-*cis*-retinoic acid. References (1) – (3) refer to methods to prepare 13-*cis*-retinoic acid. None of the claims in the instant application are compound claims to 13-*cis*-retinoic acid or methods to prepare the same. In fact, 13-*cis*-retinoic acid is commercially available (see, e.g., Sigma-Aldrich online catalog product number R3255). Thus these references merely provide background material relating to how this known compound could be prepared. Reference (4) describes methods of treating cancer with natural retinoids. The present application does not relate to the treatment of cancer. References (5)-(9) related to electrohydrodynamic dispensing devices which produce a finely divided spray of liquid droplets. The present invention claims formulations which can be dispensed from electrohydrodynamic dispensing devices (see, e.g., Example 5); however, dispensing devices are not claimed. Thus all the references merely provide background information rather than essential subject matter.

Applicants request the requirement to amend the disclosure be withdrawn or that the Examiner indicate the subject matter that is regarded as essential.

The Office Action has asserted the Applicant's amendment necessitated the new ground(s) of rejection presented in [the last] Office Action.

BUCKWALB:121084v1

- 8 -

Applicants assert that the action to make the previous Office Action final is premature. The amendments in the previous Office Action either were new dependent claims to treatment of emphysema or newly added claims to treatment of chronic pulmonary obstructive disease (COPD). The claims as initially filed were for methods and compositions for the treatment of emphysema. The new reference is related to the treatment of emphysema. This reference could have been applied to the original claims but for the fact that the patent was only granted February 4, 2003. The new reference could not have been cited earlier because it did not exist and is unrelated to the new claims added by amendment. Applicants argue this clearly was new grounds for rejection and a further arguments should be allowed and this amendment entered into the record. Review and reconsideration of the final rejection is earnestly solicited.

### CONCLUSIONS

Applicants argue that the previous final Office Action was premature and request reconsideration of the final rejection. The present amendments only delete existing claims. Moreover the date of the newly cited reference is after the priority date of the application and therefore is not a valid reference. Arguments are made that the requirement to amend the specification was unnecessary. No additional search is required and no new issues have been raised. Applicants believe the application is in condition for allowance. Entry of the amendment and favorable action on the application are respectfully requested.

No additional fees should be due with this application; however if any fee is required the Examiner is authorized to charge the fee to Deposit Account 18-1700.

If the Examiner believes that an interview will advance prosecution or aid in the favorable consideration of this amendment, the Examiner is respectfully invited to contact the applicant's representative at 605-855-6995.

Respectfully submitted,



By: Brian L. Buckwalter  
Registration No. 46,585  
Agent for Applicant

May 15, 2003

Roche Palo Alto LLC  
3431 Hillview Avenue, Palo Alto, CA 94304-1397  
Telephone 650-855-6995  
Telecopier 650-855-5322

BUCKWALB:121084v1

- 10 -